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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/669,596	09/25/2003	David Schmidt	27439-003	1315

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PILLSBURY WINTHROP SHAW PITTMAN, LLP
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EXAMINER

GHALI, ISIS A D

ART UNIT	PAPER NUMBER
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1615

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05/23/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/669,596	Applicant(s) SCHMIDT, DAVID	
	Examiner Isis A. Ghali	Art Unit 1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 28 February 2007.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-57 is/are pending in the application.
- 4a) Of the above claim(s) See Continuation Sheet is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☐ Claim(s) _____ is/are rejected.
- 7) ☒ Claim(s) 1,3,5,6,10,11,14,16,18,20,22,24,26,34 and 42 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- ☐ Certified copies of the priority documents have been received.
 - ☐ Certified copies of the priority documents have been received in Application No. _____.
 - ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|-------------------------------------------------------------------------------------------------------------------------------------|-----------------------------------------------------------------------------------------|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date <u>02/10/2004</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Disposition of Claims:

Claims withdrawn from consideration are 2,4,7-9,12,13,15,17,19,21,23,25,27-33,35-41,43-57.

DETAILED ACTION

The receipt is acknowledged of applicant's election filed 02/28/2007, and IDS filed 02/10/2004.

Claims 1-57 are pending.

Response to Election/Restrictions

1. Applicant's election without traverse of Invention I, and species of left-handed molecules, bracelet and stamina, claims 1, 3, 5, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34 and 42 in the reply filed on 02/28/2007 is acknowledged. Claim 38 is further withdrawn as it recites sugars which are right handed molecules.

2. Applicant's election with traverse of species L-carnitine amino acid in the reply filed on 02/28/2007 is acknowledged. The traversal is on the ground(s) that claims 6, 10, and 11 contain proper Markush format and the members of the Markush are few and closely related, and can be searched without serious burden on the patent examiner. This is not found persuasive because the patent examiner searches the invention mostly literally, and this makes the search extensive. Additionally, the prior art that may anticipate one species may not anticipate the other or even make it obvious.

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For example claim 36 recites carnitine only, and the prior art that teaches carnitine may anticipate/obviate claims 6, 10 and 11, but not claim 36.

The requirement is still deemed proper and is therefore made FINAL.

3. Claim 36 is withdrawn from further consideration pursuant to 37 CFR 1.142(b), as being drawn to a nonelected species (L-carnitine), there being no allowable generic or linking claim. Applicant timely traversed the restriction (election) requirement in the reply filed on 02/28/2007.

4. Claims 2, 4, 7-9, 12, 13, 15, 17, 19, 21, 23, 25, 27-33, 35, 37-41, 43-57 are withdrawn from further consideration pursuant to 37 CFR 1.142(b) as being drawn to a nonelected invention and species, there being no allowable generic or linking claim. Election was made **without** traverse in the reply filed on 02/28/2007.

Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, 26, 34, and 42 are included in the prosecution.

Specification

5. The lengthy specification has not been checked to the extent necessary to determine the presence of all possible minor errors. Applicant's cooperation is requested in correcting any errors of which applicant may become aware in the specification.

Claim Rejections - 35 USC § 112

6. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

7. Claims 16 and 18 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The claims recite the expressions "ABS", "light polarizing film" and "linear low density film" that do not set out the metes and bounds of the claim. Recourse to the specification does not define the expressions.

Claim Rejections - 35 USC § 102

8. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

9. Claims 1, 3, 5, 6, 10, 11, 14, 16, 18, 20, 22, 24, and 42 are rejected under 35 U.S.C. 102(e) as being anticipated by US 6,475,514 ('514).

US '514 discloses transdermal patches for administration of nutrient supplement to a subject wherein the patch comprises amino acids (abstract; col.2, lines 47-51; 65-

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67). The amino acids included hydroxyproline that is claimed by applicant by claim 6 as left-handed molecule, further including alanine, valine, phenylalanine, etc. (col.6, lines 65-67; col.7, lines 1-2, 60-67). The patch further includes L-carnitine (col.8, line 8). The patch comprises backing layer, which reads on the claimed substrate, made of polyester fabric (col.9, lines 5-6; col.11, lines 45-59). The patches are stored in pouches comprising polypropylene (col.12, lines 27-37). The patch further comprises adhesive to affix the patch to the skin (col.9, lines 55-57). The patch comprises additives such as permeation enhancers including glycols, preservatives including alcohols, and plasticizers (col.13, lines 12-15, 49-52; col.14, lines 10-12). The capability of the left-handed molecule of causing beneficial effect as claimed by claim 5 and improving subject stamina as claimed by claim 42 are inherent function of the specific molecule.

Claim Rejections - 35 USC § 103

10. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

11. Claim 26 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of US 5,651,973 ('973).

The teachings of US '514 are discussed as set forth in this office action.

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However, US '514 does not teach the patch is embodied in a bracelet as claimed by claim 26.

US '973 teaches transdermal patch that is attached to the back of suitable article such as wrist band or bracelet in order to eliminate the contact between irritating elements in the patch and the skin (col.11, lines 20-25).

Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising plurality of amino acids including hydroxyproline and L-carnitine as disclosed by US '514, and attach the patch to a bracelet as disclosed by US '973, motivated by the teaching of US '973 that when the patch is attached to a bracelet it eliminates skin irritation, with reasonable expectation of having patch comprising amino acids and attached to a bracelet to effectively deliver amino acids to the wearer without irritating the skin.

12. Claim 34 is rejected under 35 U.S.C. 103(a) as being unpatentable over US '514 in view of 6,558,695 ('695).

The teachings of US '514 are discussed as set forth in this office action.

Although US '514 teaches additives, however, US '514 does not teach the specific additives as claimed by claim 34.

US '975 teaches transdermal patch comprising glycerin because it acts as irritation mitigating agent and eliminates the possibility of skin irritation (abstract; col.15, lines 14-20).

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Therefore, it would have been obvious to one having ordinary skill in the art at the time of the invention to provide patch comprising amino acids including hydroxyproline, L-carnitine, and additives as disclosed by US '514, and replace the additives with glycerin, or further add glycerin to the additives as disclosed by US '695, motivated by the teaching of US '695 that glycerin acts as irritation mitigating agent and eliminates the possibility of skin irritation, with reasonable expectation of having patch comprising amino acids and glycerin to effectively deliver amino acids to the wearer without irritating the skin.

13. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure. US 2002/0072501 teaches L-carnitine to increase energy.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Isis A. Ghali whose telephone number is (571) 272-0595. The examiner can normally be reached on Monday-Thursday, 7:00 to 5:30.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR.

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Status information for unpublished applications is available through Private PAIR only.

For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Isis A Ghali
Primary Examiner
Art Unit 1615

IG

Isis Ghali

**ISIS GHALI
PRIMARY EXAMINER**